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GOVERNMENT NOTICES

Australian Government

Department of Health

Office of the Gene Technology Regulator

28 April 2021

Invitation to comment on a clinical trial of a genetically modified Herpes virus for the treatment of cystic fibrosis

The Gene Technology Regulator is assessing an application from Novotech (Australia) Pty Limited to conduct a clinical trial, under limited and controlled conditions, of a genetically modified *Herpes simplex virus* for the treatment of cystic fibrosis. The trial is proposed to take place at hospitals within Australia and up to 15 cystic fibrosis patients would receive the treatment.

The Regulator has prepared a Risk Assessment and Risk Management Plan (RARMP) for this application and welcomes written submissions on issues relating to the protection of human health and safety and the environment before making a decision on whether or not to issue the licence. The consultation RARMP and related information can be obtained via the contacts below. Submissions should reference DIR 181 and be received by **31 May 2021**.

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